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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,598	11/03/2005	Pierrette Gaudreau	BCF-001	7604

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EXAMINER
BRADLEY, CHRISTINA

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,598	GAUDREAU, PIERRETTE	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-35,39 and 40* is/are pending in the application.

4a) Of the above claim(s) *31-35 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-30 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2007, 2/7/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 17-30, and 39, in the reply filed on 5/25/2007 is acknowledged. Claims 17-35, 39 and 40 are pending; claims 31-35 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Objections

2. Claims 22-30 and 39 are objected to. Claims 22, 25, 28 and 39 recite "formula X:Tyr-A2...". There are two alternative interpretations for this limitation. First, the claim may be drawn to formula X which is defined as Tyr-A2..... That is "X" is the numeric identifier of the formula or part of the name of the formula. Alternatively, the formula is a chemical comprising X:Tyr which is not defined in the specification or the claim. Paragraph 0047 of the specification makes it clear that the former interpretation is intended. In order to clarify the claim, Applicant should insert a hard return after "formula X:" or delete the X altogether. For the purposes of examination, the claims are interpreted as if "X" is the numeric identifier of the formula.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 17-22, 28 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaudreau (U.S. Patent No. 5,854,216, cited reference A1 on the Information Disclosure Statement filed 2/7/2007).

5. Regarding claims 17-21, Gaudreau teaches the growth hormone releasing hormone (GHRH) analogue:

Tyr-D-Ala^{2}-Asp-Ala-Ile-Phe-Thr-Asn-Ser- D-Tyr^{10}-Arg-Lys-Val-Leu-D-Ala^{15}-Gln-Leu-Ser-Ala-Arg-Lys- Lys^{22}-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH_2

(Table 10, compound 8, also referred to in Table 11 as (D-Ala^{2}, D-Tyr^{10}, D-Ala^{15}, Lys^{22})hGRF(1-29)NH_2) which is identical to the GHRH analogue in claim 21 and a species in the genus of claims 17-20. With respect to the formula in claim 17, A30 is a bond.

6. Regarding claims 22, 28 and 39, Gaudreau teaches methods of treating conditions such as burns by administering compounds comprising a fluorophore, linker and, individually, the following peptide GHRH analogues that fall within the claimed genus:

Tyr-D-Ala^{2}-Asp-Ala-Ile-Phe-Thr-Asn^{8}-Ser-D-Tyr^{10}-Arg-Lys-Val-Leu-Gly^{15}-Gln-Leu-Ser-Ala-Arg-Lys^{21}-Leu^{22}-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH_2

wherein A2 is D-Ala, A8 is Asn, A10 is D-Tyr, A15 is Gly, A21 is Lys, A22 is Leu and A30 is a bond (claim 3, column 46, lines 4-7);

Tyr-D-Ala^{2}-Asp-Ala-Ile-Phe-Thr-Asn^{8}-Ser-D-Tyr^{10}-Arg-Lys-Val-Leu-D-Ala^{15}-Gln-Leu-Ser-Ala-Arg-Lys^{21}-Leu^{22}-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH_2

wherein A2 is D-Ala, A8 is Asn, A10 is D-Tyr, A15 is D-Ala, A21 is Lys, A22 is Leu and A30 is a bond (claim 3, column 46, lines 8-11); and

Tyr-Ala^{2}-Asp-Ala-Ile-Phe-Thr-D-Asn^{8}-Ser-Tyr^{10}-Arg-Lys-Val-Leu-Gly^{15}-Gln-Leu-Ser-Ala-Arg-Lys^{21}-Leu^{22}-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH_2

wherein A2 is Ala, A8 is D-Asn, A10 is Tyr, A15 is Gly, A21 is Lys, A22 is Leu and A30 is a bond (claim 3, column 46, lines 36-39).

7. In order to treat conditions such as burns, these compounds must be combined with a pharmaceutically acceptable carrier. That is, in order to topically administer a peptide-based drug, the drug must be combined with a gel or cream, for example. Therefore, the limitation in claims 22, 28 and 39 that the composition include a pharmaceutically acceptable carrier is implicit in the teaching of Gaudreau.

8. With respect to claims 17-21, Gaudreau does not teach that the GHRH analogue has an *in vitro* potency index substantially higher than the *in vitro* potency index of a native hGHRH(1-29). With respect to claim 28, Gaudreau does not teach that the pharmaceutical compositions stimulate the secretion or synthesis of growth hormone in a mammal. Because the chemical structure of the species taught by Gaudreau is identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. If the composition is physically the same, it must have the same functional properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) See MPEP § 2112.01. Examiner cannot however determine whether or not the GHRH analogue taught by Gaudreau inherently possesses properties which anticipate or render obvious the claimed invention but has

basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 17-30 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaudreau (U.S. Patent No. 5,854,216, cited reference A1 on the Information Disclosure Statement filed 2/7/2007).

11. Gaudreau teaches compounds of the formula Ra-X-Rb wherein Rb represents a broad genus of GHRH analogue peptides covalently linked to a fluorophore (Ra) via a linker (X). These compounds are useful as selective peptide markers in biological, pharmacological and anatomical studies (column 2, lines 44-49 and column 3, line 1 through column 4, line 58). In addition, Gaudreau teaches that some GHRH analogue peptides can be used to treat conditions such as hypothalamic pituitary dwarfism, burns, osteoporosis, renal failure, non-union-bone fracture, wounds, post-surgical problems, lactation failure, female infertility, cachexia, T-cell immunodeficiencies, neurodegenerative conditions and GRF receptor-dependent tumors (column 5, lines 12-36).

12. As stated above, Gaudreau teaches the GHRH analogue consisting of:

Tyr-D-Ala^{2}-Asp-Ala-Ile-Phe-Thr-Asn-Ser- D-Tyr^{10}-Arg-Lys-Val-Leu-D-Ala^{15}-Gln-Leu-Ser-Ala-Arg-Lys^{21}-Lys^{22}-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH_2

wherein A2 is D-Ala, A8 is Asn, A10 is D-Tyr, A15 is D-Ala, A21 is Lys, A22 is Lys and A30 is a bond (Table 10, compound 8, also referred to in Table 11 as (D-Ala^2, D-Tyr^{10}, D-Ala^{15}, Lys^{22})hGRF(1-29)NH_2). This peptide is identical to the peptide species recited in claims 21, 24, 27 and 30, and is a species within the peptide genus recited in claims 17-20, 22, 23, 25, 26, 28, 29 and 39.

13. Gaudreau does not teach a pharmaceutical composition comprising a GNRH analog consisting of the above peptide and a pharmaceutically acceptable carrier.

14. It would have been obvious to make a pharmaceutical composition comprising a GHRH analogue consisting of the peptide (D-Ala^2, D-Tyr^{10}, D-Ala^{15}, Lys^{22})hGRF(1-29)NH_2, and a pharmaceutically-acceptable carrier. The skilled artisan would have been motivated to do so based on the teaching of Gaudreau that (D-Ala^2, D-Tyr^{10}, D-Ala^{15}, Lys^{22})hGRF(1-29)NH_2 possesses biological activity: the analogue has a binding affinity to the receptor in rat adenopituitary cells equivalent to that of wild type hGRF(1-29)NH_2 (Table 11). In addition, Gaudreau teaches that substitutions by D-amino acids increase the *in vitro* and *in vivo* metabolic stability of the peptide (column 24, lines 23-26). The skilled artisan would have been further motivated to combine the peptide with a pharmaceutically acceptable carrier suitable for the specific condition to be treated and the desired mode of administration (i.e. topical for the treatment of burns and subcutaneous injection, intravenous or oral osteoporosis, for example). There would have been a reasonable expectation of success given that the GHRH analogue peptide has biological activity. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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